novacare

APM 440 plus

Operating instructions

Antidecubitus-
Alternating pressure

With the ***nova*care® Alternating pressure system APM 440 *plus***, you have acquired a Decubitus-Treatment system..

A good decision
Your novacare® – Team

Please read the following operating instructions carefully and read the caution notice before commissioning the system.

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1. The System:

consists of a high-quality control unit with a membrane pump and a mattress replacement with 20 air cells (of which 7 narrow cells are located in the heel area)) arranged in a transverse manner and a base mattress. The mattress replacement system is additionally equipped with a high-quality, bi-elastic, steam-permeable, water tight wraparound protective cover.

2. Scope of supply:

- Alternating pressure system **APM 440 plus**
- Alternating pressure mattress replacement
- Carry bag
- Operating instructions

3. Indication / Contraindication:

Indication :	Treatment and prevention of pressure ulcers and decubitus
Contraindication :	alternating pressure should not be used for patients in pain or patients with a low pain threshold. Use the device in the static mode for such patients.

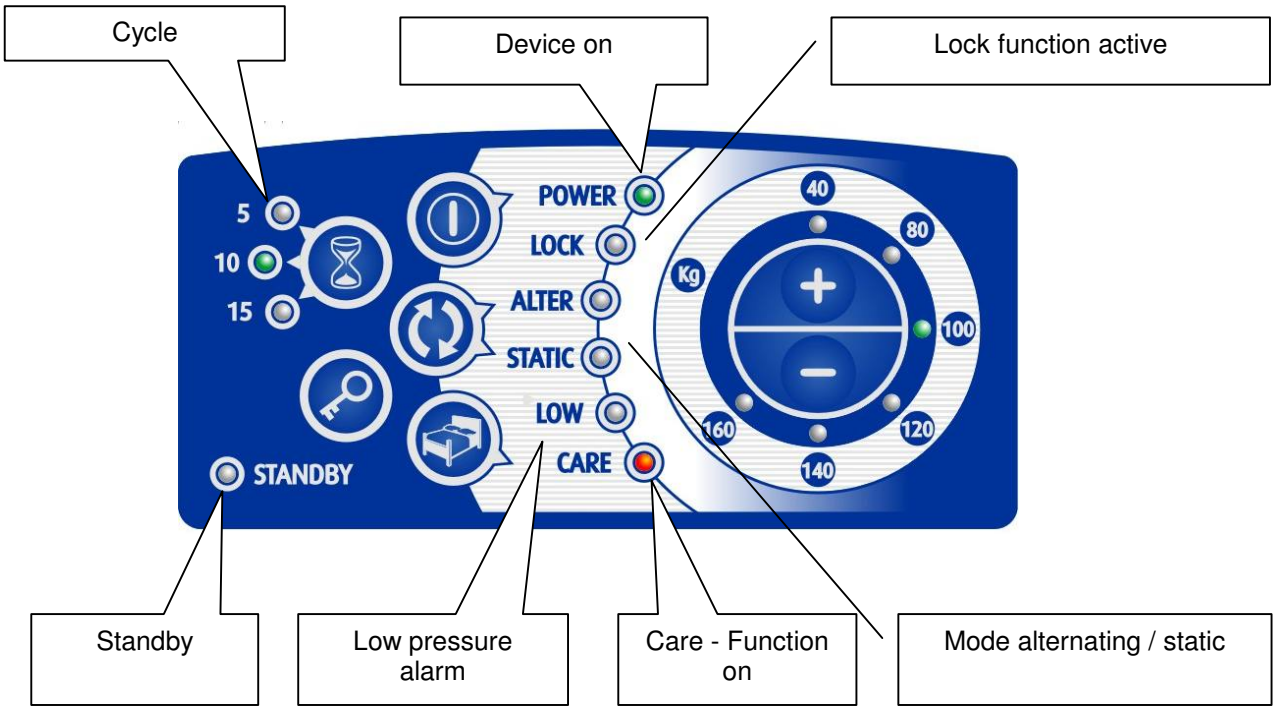
4. Severity of Decubitus / Area of application :

The **novacare® Alternating pressure system APM 440 *plus*** is recommended for Decubitus up to Grade IV (according to Seiler).

5. Maximum load / Patient weight

The **novacare® Alternating pressure system APM 440 *plus*** has been designed for a maximum patient weight of **180 kg**.

6. Operating elements/ Controls/ Key layout / LED-Displays :



Key layout:

Power switch

Cycle setting

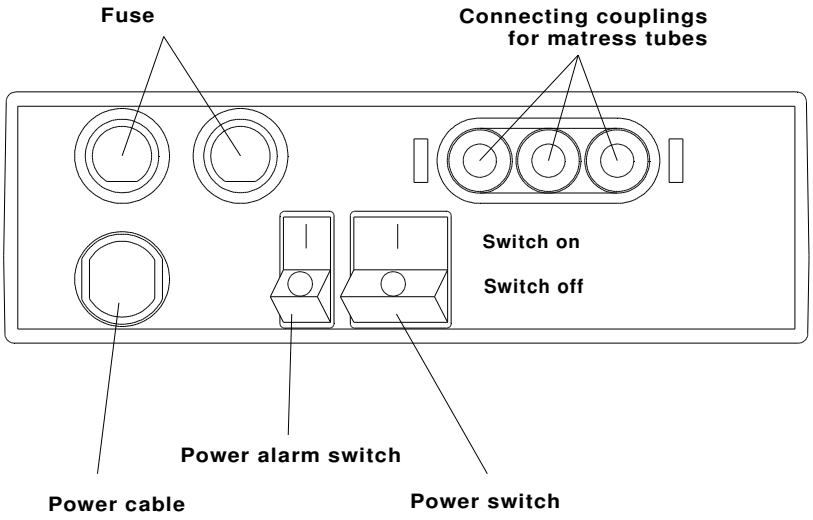
Pressure regulator

Activating the Care-Function

Operating mode selector switch Static / Alternating

Unlocking the keyboard

7. *Operating elements / Connections*



8. *Preparing the system for commissioning :*

1. First, remove the existing mattress on the bed of the patient. Now, take the entire mattress system from the carton and keep it on the grid of the bed of the patient.
2. Remove the control unit from the carton and attach it to the foot end of the bed with fixing hooks.

   ! Due to the automatic foldable clamps the system fits to the foot of the bed, which provide a secure hold. Once the control unit is detached the clamps automatically fold back to the starting position.
3. Please ensure that the connecting tube is located at the foot end of the bed.
4. Roll out the base mattress and push it inside a separate chamber below the cell chambers. This chamber is equipped with a wraparound cover.
5. Fix the complete mattress overlay with 6 fastening belts to the bed grid.
6. Now, connect the Trio-Plug of the mattress in-feed tube (remove the transport lock beforehand) with the connector to the underside of the control unit. Please ensure that the plug is engaged properly.
7. Insert the power plug into a 220 V socket.
8. Now, activate the main power switch on the underside of the unit.
9. The unit displays “STANDBY“ to indicate that it is ready for operation. Switch on the control unit by pressing the key (power).
10. Now, depending upon the desired operating mode, set the unit using the mode key to alternating mode (LED – Display “ALTER“ glows) or the static mode (LED – Display “STATIC“ glows)
11. The process of inflation takes approx. 20 minutes.

12. It is not necessary to set the pressure to suit the patient. The comfort setting automatically adjusts to the pressure of the patient in the sleeping position. Select the central position for the standard setting; conduct the practical test (see description : practical test) and correct, if necessary, individually (observe the key locking function).

13. The system is ready to be operated, if the display 'LOW' (see alarm functions) goes out.

Attention :

When raising the head rest portion of the bed please increase mattress pressure by 1 to 2 degrees

9. Setting of patient weight:

Please check the numbers on the dial when setting the best suitable patient cell pressure.

Please consider that these pre-settings are recommendations only. Please conduct the „Practical Test" in any case and make individual adjustments until you determine the correct setting for the patient in question.

10. Static mode:

The unit can be operated in static mode for special applications (for example pain patients, patient transport). In static mode all cells are ventilated with the same pressure, the alternating effect is stopped. Please note that due to the cyclic adjustment of the drive the switching to static mode may take up to max 9 to 10 minutes.

We recommend to set the pressure to 1-2 settings lower than indicated on the dial scale. Conduct a system check as well.

LED lights up immediately after static mode has been initiated. Static mode adjusts automatically inside the drive cycle.

11. Keyboard locking function

In order to prevent unauthorized changes in the default settings, the **APM 440 plus** control unit is equipped with an automatic keyboard locking system. It automatically becomes active after 3 minutes.

Cancel the keyboard locking function by pressing the key with a symbol of a key on it. Keep the key pressed for approx. 5 seconds till the LED – Display "LOCK" goes out.

Now, depending upon the desired operating mode, the unit can be set to alternating mode using the mode key (LED – Display "ALTER" glows) or the static mode (LED – Display "STATIC")

12. Alarm function:

The ***nova*care® APM 440 plus Alternating pressure system** features an alarm system. It visually and acoustically displays low pressure and power failure as well as interruption in electricity.

Upon commissioning, the system is in low pressure during the inflation phase up until it has been completely vented. The optical low pressure indicator „LOW“ lights up. The acoustic alarm features a delay function, which considers the duration of inflation. The alarm automatically activates after about 45 minutes.

If, for example, during re-positioning the pressure sinks below 20 mm/Hg for a short time, the acoustical alarm changes to a 5 minute delay. If there is still low pressure after this delay, the alarm is activated.

This avoids a disturbing, undesired alarm.

Description of the acoustic alarm signal:

Power failure: pulsed individual Beep-Signal
beep – beep - beep
Low pressure: pulsed double Beep-Signal
beepbeep - beepbeep - beepbeep -

Disconnecting the acoustic alarm:

Power failure: Shut down alarm switch located at the bottom of the unit to „0“ .
Low Pressure: Shut down control unit (ON/OFF) or pull the power plug. If applicable set alarm switch to „0“ .

13. Using the Care-Function

The control unit of **APM 440** *plus* is equipped with a CARE function. On activating this function, all chambers of the mattress system are filled with maximum system pressure for 30 minutes. After 30 minutes, the system automatically switches over to the alternating pressure mode for the safety of the patient.

This function simplifies the process of shifting patients from one location to another during treatment.

14. Practical Test:

In case of optimum and correct pressure, you should be able to pass your hand between the patient and an inflated cell without any difficulty.

15. System operations with one cell extracted:

The mattress overlay of **APM 440 plus** allows operations even if the cell is removed. For doing so, loosen the CPC-Coupling of the cell in question, remove the cell and lock the coupling with a CPC-Sealing plug. A CPC-Plug (Art.-No.: 991016) is supplied with the system. Please ensure that the plug is engaged properly.

Now the system can be used once again without difficulty.

The cell thus removed can be inserted back in exactly the opposite sequence

16. Alternative positioning of the control unit:

The control unit of **APM 440 plus** can also be operated in a horizontal position, if a suspension is not desirable or not possible at the head end. Legs provided for the control unit enable secure positioning and provide adequate gap for air circulation. In any case, see to it that there is proper air circulation and that the air filter is not blocked (e.g. in case of floors with thick carpets).

17. Transportation of patients / operation without power

In case of separation from power supply (i.e. patient transportation) pressure within the alternating pressure mattress can be maintained for a certain amount of time. Two options apply. First switch the system to static mode.

a) Pull the power plug. System pressure is maintained for 15-20 minutes and is then gradually reduced.
b) Separate the control unit from the alternating pressure mattress. Release and remove the Trio plug at the control unit. Put the cap onto the socket and ensure that the it catches properly. This has to be done quickly in order to avoid loss of pressure. The system maintains the pressure for several hours. We recommend to check the overlay for sufficient pressure in regular intervals.

18. Technical data :

• *control unit :*	*weight*		*5.5 kg*
	dimensions :		*30 x 22 x 12 cm*
	length power cord		*3 m*
	rated speed :		*AC 220-240 V / 50 Hz*
			Max. 0.2 A
	Fuse rating :		*TIAH 250 VAC 1A*
	protection class :		*Type BF / Class I*
• *Mattress :*	*weight :*		*11,8 kg*
	dims (w/o base) :		*200 x 90 x 24 cm*
	material (cover)		*PU*
• *cells :*	*dims :*		*90 X 26 X 22 cm*
	material		*Nylon, PU-coated*
• *Max. infl .pressure w/o weight*			*75 – 85 mm Hg*
• *Min. infl. pressure w/o weight*			*20 mm Hg*
• *cycle*			*5 / 10 / 15 minuts*
• *surrounding conditions:*			
	Rel. Air humidity		*20 % – 90 %*
	Temperature	*operation*	*5 °~ 55 °C*
		Storage	*-10 °~ 65 °C*

19. Technical safety:

- Testing according to DIN EN 60601-1-2:2001
- Testing according to DIN EN 60000-3-2:1995
- Testing according to DIN EN 60000-3-3:1995
- Fire test to DIN EN 597/1 and DIN EN 597/2 (Cell)
- California – Firetest Class I (Cover)
- 2 Membrane compressors
- Tension relief of the power cable
- Splash-proof
- Alarm function
  - Low pressure alarm, optical
  - Power loss failure alarm, acoustic
- CPR-Emergency valve
- Automatic foldable holding clamps

20. PracticalTesting for toxicological harmlessness and biocompatibility (compliance of standards)

- DIN EN ISO 10993-1:1998
- DIN EN 71
- ASTM F 963-96a

21. CPR - Valve :

novacare® alternating pressure system **APM 440** plus are equipped with a CPR emercency valve It facilitates an quick deflation within seconds, for example to conduct a resuscitation. In this case set the valve to switch position „open“.

22. Caution :

- Protect the control unit from humidity and direct wetness
- Keep the tubes free of bends
- Do not use the system in the proximity of a source of heat
- Pull out the power plug while moving the bed.
- Never pull the cable.
- Sharp objects must be kept away. Do not fix the overlay with inappropriate means.
- Do not use the system in the proximity of inflammable gases (risk of explosion)
- Use only genuine spare parts and consumables.

23. Maintenance / Inspection

The ***nova*care® alternating pressure system APM 440** ***plus*** is considered to be a medical device according to RL 93/42 and MPG. Follow these statutory regulations while using the device.

Maintenance at regular intervals is necessary to preserve the function of ***nova*care® Alternating pressure system APM 440** ***plus***. This must be undertaken earliest after 10 and latest after 14 months from the date of purchase.

Maintenance / inspection is conducted by the manufacturer or by his authorized contractor at a charge.

If maintenance / inspection is not conducted at all or is conducted not as per schedule or not by an authorized agency, then the warranty and warranty claims are no longer valid. Damages or any other loss of function arising from lack of maintenance or untimely maintenance / inspection or interference by an unauthorized agency likewise leads to loss of warranty and warranty claims (see Warranty)

The following measures are to be implemented during maintenance / inspection:

- Replace the membrane unit
- Replace the air filter
- Replace the synchronous motor
- Conduct function test / function inspection
- Sealing of the case and attaching an inspection sticker
- Protective conductor check in accordance with DIN VDE 0751

Maintenance / inspection undertaken by the Service department of novacare gmbh is recorded and documented.

24. Hygiene

Systems designed for reuse must be prepared on the basis of locally valid directive, laws or regulations “for Hospital hygiene and Infection prevention“.

Already validated procedures and hygiene schedules, if any, must be applied for this preparation.

Please act according to your locally valid hygiene directives and the respective list of disinfectants for disinfecting the products and use only disinfectants listed in them. Follow the instructions for use prescribed by the respective manufacturer.

Warranty claims become null and void if inappropriate and unlisted preparations are used or are used inappropriately.

We recommend our cleaning service. Please inquire about the applicable charges.

25. Care, cleaning, disinfection

The *nova*care® APM 440 plus alternating pressure system wraparound protective cover can be cleaned chemical-thermally by machine up to 60°. For disinfection we recommend the use of an approved disinfection cleaning additive. To increase the life span clean cells by spray/wipe disinfection. In special cases chemical-thermal cleaning is possible as well.

Please ensure that the cell body opening are shut when cleaned by machine.

For use, follow the recommentions of the respective manufacturer.

This measure might not replace hygiene regulations currently valid in your country and should be applied only in special cases (i.e. interim cleaning of acute contamination).

26. Warranty :

- The warranty is based on statutory regulations.
- Every warranty is excluded immediately, if the goods supplied by us are processed, handled or modified by other parties without our consent or if our operating instructions are not followed. If the seals are damaged, it will be assumed that the aforesaid activities have been carried out.
- For medical devices as understood by the EG-Directive 93/42/EEC, whose usage is subject to regular service and maintenance, a warranty can be offered only if the service intervals prescribed by the manufacturer are adhered to.
- As far as warranty claims are accepted and if during the subsequent inspection it is found that the damages are of wear and tear or are not subject to warranty, then we are empowered to claim the expenses (inspection, transport costs etc.) from the customer.
- The use of parts or individual components of other systems or products or combinations thereof are not permissible. Warranty claims cease to exist for any damage resulting from this, which must be borne by the user

27. Designation / Article-No. :

- Designation ***:*** ***nova*care® Alternating pressure system APM 440 plus**
- Article No.: **991500 N**

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